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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,361	03/20/2001	Natalia I. Afanassieva	AFAN-003	2342

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EXAMINER

PASS, BARRY

ART UNIT

PAPER NUMBER

3737

DATE MAILED: 08/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/817,361

Examiner

Barry Pass

Applicant(s)

AFANASSIEVA, NATALIA I.

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 March 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Objections*

1. Claim 8 objected to because of the following informalities: In line 1 reference is made to claim "58." For the purpose of examining the claim the examiner will consider this to read claim "6." Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 2 is rejected under the second paragraph of 35 U.S.C. 112 for being an improper Markush claim. The relevant part of the claim should read ".....selected from *the group consisting of* a shaped probe, a needle probe....., *and* a catheter probe." This is the form of the claim that will be assumed for the purpose of examination. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kittrell et al. US 5,304,173. Kittrell et al. discloses a spectral diagnostic system consisting of a percutaneous laser catheter (abstract) operating with a plurality of wavelengths, in particular consisting of an IR source (column 7, line 64), fiberoptic light guide, coupling means for the fiber optic, IR detector for reflected or otherwise altered radiation received from a biological sample, spectrum analyzer (column 19 line 41) and spectrofluorimeter (column 2 line 59), and quantitative analysis of the peaks of the detected spectra to compare healthy and diseased tissue (column 24-25). Inherent to an IR source and IR detector is the capability of operating at any wavelength in the IR range; inherent to a spectrofluorimeter and modern spectrum analyzers is the means to perform a Fourier spectral analysis of the detected radiation.

6. In the alternative, it would have been obvious to someone of ordinary skill in the art at the time of the invention that spectral analysis of detected IR radiation can be performed with a standard Fourier spectrophotometer operating in the range of 2.5 to 20 micron, or in any desired range to determine individual frequency components of the composite spectrum and their characteristics that reflect the state of the biological sample being analyzed. It also would have been obvious that catheter systems must include means for changing probes.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-4 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell in view of Clift US 5,452,716. Kittrell et al. discloses a spectral diagnostic system consisting of a percutaneous laser catheter (abstract) operating with a plurality of wavelengths, in particular consisting of an IR source (column 7, line 64), fiberoptic light guide, coupling means for the fiber optic, IR detector for reflected or otherwise altered radiation received from a biological sample, spectrum analyzer (column 19 line 41) and spectrofluorimeter (column 2 line 59), and quantitative analysis of the peaks of the detected spectra to compare healthy and diseased tissue (column 24-25). Kittrell does not specifically teach Fourier Transform IR spectroscopy (FTIRS). Clift teaches in column 2, lines 45-49, the use of ATR and FTIRS for detected radiation from a biological sample. It would have been obvious to someone of ordinary skill in the art at the time of the invention to use a FTIRS for spectral analysis of the radiation reflected from a biological sample to produce a detailed and essential description of that radiation and hence of the state of the biological sample.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell as applied to claim 1 above, and further in view of Haaland et al. US 5,596,992. Kittrell discloses the system

as recited in claim 1. Kittrell does not teach spectral analysis with a probe using attenuated total reflectance (ATR). Haaland et al. teach in column 6 near-infrared in vivo fiber-optic probe for in vivo detection of cancer and for biopsies to classify cells, in column 6-7 ATR employed in the mid-infrared to potentially increase sensitivity of cytology, histopathology, and in-vivo surface sampling, an infrared microscope coupled with an ATR used for cytology and histopathology samples. Accordingly, it would have been obvious to someone of ordinary skill in the art at the time of the invention to adapt the laser probe system for spectral analysis of Kittrell et al. to perform ATR spectroscopy to increase sensitivity of tissue analysis.

10. Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell et al. in view of Haaland et al., further in view of Clift. Kittrell et al. discloses a spectral diagnostic system using quantitative analysis of the peaks of the detected spectra from healthy and diseased tissue (column 24-25). Haaland et al. teach in column 6 near-infrared in vivo fiber-optic probe for in vivo detection of cancer and for biopsies to classify cells, in column 6-7 ATR employed in the mid-infrared to increase sensitivity of cytology, histopathology, and in-vivo surface sampling. Kittrell et al. and Haaland et al. do not teach Fourier analysis of detected radiation. Clift teaches in column 2, lines 45-49, the use of ATR and FTIRS for detected radiation from a biological sample. It would have been obvious to someone of ordinary skill in the art at the time of the invention to use ATR and FTIRS for spectral analysis of the radiation reflected from a biological sample to produce a detailed and essential description of that radiation and hence of the state of the biological sample. Further, it is well known in the art that quantitative analysis of spectra requires analysis of peak position, height, and enclosed area, and comparison of spectra would include ratios of these parameters.

*Conclusion*

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


Stevenson et al. US 5,585,634 teach an optical probe for ATR spectroscopic monitoring of materials.

Mattson US 5,491,551 teaches the standard technique of FTIR spectroscopy for providing a reflectance or absorbance spectrum of a sample.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barry Pass whose telephone number is (703) 305-0726. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on (703) 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0758 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0873.

  
Barry Pass  
August 8, 2002

  
George Manuel